

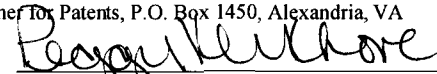
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	MITANI, et al.	Examiner:	A.M. Bertagna
Serial No.:	10/532975	Group Art Unit:	1637
Filed:	April 28, 2007	Docket:	20078.0005USWO
Title:	PROCESS FOR AMPLIFYING NUCLEIC ACIDS		

CERTIFICATE OF TRANSMISSION

I hereby certify that this paper is being transmitted by EFS Web to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 3, 2010.

By:



Name: Peggy Kerkhove

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form SB08 are brought to the attention of the Examiner. Copies of any foreign patent documents or "Other Documents" are enclosed.

A concise explanation of the relevance of each non-English language document or other information is as follows (37 C.F.R. §(a)(3)):

WO 97/00330 corresponds to JP 11-509406. A concise explanation of the Taiwanese Office Action is enclosed. A full English translation of the Trial Decision (NPL4) is enclosed.

The following is a concise explanation of the enclosed Prosecution documents (NPL5 & NPL6). Exhibit No. 1 and Exhibit No. 3 mentioned below are omitted because they are the same as the related documents or were evidential documents at the time of the trial for invalidation and have been already submitted

As in the case of Mukou (Invalidation) 2008-800091, which is the original trial, the demandant argues that the present invention is obvious on the ground of the combination of Demandant's Exhibit No. 1 (JP2000-37194A, which is a Japanese publication corresponding to EP097 1039A2 (Rabbani) of ENZO DIAGNOSTICS, INC.) and Exhibit No. 3 (JP 3313358 B). However, Exhibit No. 3 is a document relating to the LAMP method similar to Nucleic Acid Research 2000; 28(12):e63 (Notomi), and Molecular and Cellular Probes (June 2002) 16(3):223-229 (Nagamine). It is clear that the mechanism for the formation of the intermediate is different between Rabbani and JP 3313358 B (Demandant's Exhibit No. 3), and that efficient amplification by improving Rabbani's intermediate formation reaction could not have been expected from

combining Rabbani with JP 3313358 B.

The demandant, in the Mukou (Invalidation) 2008-800091 (invalidation trial case of JP 3867926), argues that the present invention is obvious on the ground of newly cited Demandant's Exhibit Nos. 9 to 11. However, since Demandant's Exhibit Nos. 9 to 11 are documents relating to the LAMP method, the present invention is not obvious. The summary of the argument by the demandant and the refutation by the demandees (applicants of the present application) are as follows:

#### Argument by Demandant

Primers satisfying the condition of the mathematical formula of the present invention are described in Demandant's Exhibit Nos. 9 to 11 (LAMP method).

In addition, an example of an amplification reaction in the absence of Outer Primer (OP-) is described in Example 4 of Demandant's Exhibit No. 9.

Since amplification is observed even in the absence of Outer Primer (OP-), it is easy to apply Demandant's Exhibit No. 3 (LAMP method) to Demandant's Exhibit No. 1 (ENZO method).

#### Refutation by Demandees

Demandant's Exhibit Nos. 9 to 11 are all relating to the LAMP method (Outer Primer is indispensable).

Example 4 of Demandant's Exhibit No. 9 is also an example showing necessity of Outer Primer

Awareness of a person skilled in the art

- When a person skilled in the art reads the whole text and Example 4 of Demandant's Exhibit No. 9, he or she realizes necessity of Outer Primer and does not willingly apply Exhibit No. 3 (LAMP method) to Demandant's Exhibit No. 1 (ENZO method).
- Further, credibility of Example 4 is questionable and it is inappropriate for the evidence.

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the Filing Date, before the mailing date of a First Office Action on the merits, or before the mailing date of a First Office Action on the merits after the filing of a request for continued examination under 37 C.F.R. §1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a Final Rejection or Notice of Allowance, and

- ☐ the requisite Statement is below, OR
- ☒ the requisite fee of \$180.00 under Rule 1.17(p) is included herein, or
- ☐ (3) after the mailing date of a Final Rejection or Notice of Allowance but on or before the payment of the Issue Fee, AND the requisite Statement is below AND the requisite fee of \$180.00 under Rule 1.17(p) is included herein.

### STATEMENT

Applicants hereby state that:

- ☐ Each item of information contained in the Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart application or by the USPTO in a related application not more than three months prior to the filing date of the Information Disclosure Statement
- ☐ If this box is checked, Applicant provides the following:
- Certification Under 37 C.F.R. §1.704(d)**
- each In accordance with 37 C.F.R. §1.704(d), the undersigned hereby certifies that item listed on the enclosed Form SB08 was first cited in a communication from a foreign patent office in a counterpart application, and that this communication was not received by any individual designated in 37 C.F.R. §1.56(c) more than thirty (30) days prior to the filing of this Information Disclosure Statement.
- ☐ The Examiner is hereby advised of the following co-pending U.S. applications. A copy of each U.S. patent application publication (if published) or application (if not published) is enclosed.

Application No.

Filing Date

Group

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form SB08, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

**FEE AUTHORIZATION**

Please charge any required fee or credit overpayment to Deposit Account No. 50-3478.

Respectfully submitted,

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Dated: March 3, 2010

By: 

Douglas P. Mueller  
Reg. No. 30,300

DPM/pjk